

regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section; or

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

#### § 71.100 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 71 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 71 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 71.0, 71.2, 71.4, 71.6, 71.7, 71.9, 71.10, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.47, 71.51, 71.52, 71.53, 71.55, 71.59, 71.65, 71.71, 71.73, 71.74, 71.75, 71.77, 71.99, and 71.100.

### Subpart H—Quality Assurance

#### § 71.101 Quality assurance requirements.

(a) *Purpose.* This subpart describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this subpart, “quality assurance”

comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.

(b) *Establishment of program.* Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of §§ 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee’s activities including procurement of packaging. The licensee shall apply each of the applicable criteria in a graded approach, i.e., to an extent that is consistent with its importance to safety.

(c) *Approval of program.* Before the use of any package for the shipment of licensed material subject to this subpart, each licensee shall obtain Commission approval of its quality assurance program. Using an appropriate method listed in § 71.1(a), each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied, by submitting the description to: ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

(d) *Existing package designs.* The provisions of this paragraph deal with packages that have been approved for use in accordance with this part before January 1, 1979, and which have been designed in accordance with the provisions of this part in effect at the time of application for package approval. Those packages will be accepted as having been designed in accordance with a quality assurance program that satisfies the provisions of paragraph (b) of this section.

(e) *Existing packages.* The provisions of this paragraph deal with packages that have been approved for use in accordance with this part before January 1, 1979; have been at least partially fabricated prior to that date; and for which the fabrication is in accordance

with the provisions of this part in effect at the time of application for approval of package design. These packages will be accepted as having been fabricated and assembled in accordance with a quality assurance program that satisfies the provisions of paragraph (b) of this section.

(f) *Previously approved programs.* A Commission-approved quality assurance program that satisfies the applicable criteria of Appendix B of Part 50 of this chapter, and that is established, maintained, and executed with regard to transport packages, will be accepted as satisfying the requirements of paragraph (b) of this section. Before first use, the licensee shall notify the Director, Spent Fuel Project Office, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, of its intent to apply its previously approved Appendix B program to transportation activities. The licensee shall identify the program by date of submittal to the Commission, Docket Number, and date of Commission approval.

(g) *Radiography containers.* A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of § 34.31(b) or equivalent Agreement State requirement, is deemed to satisfy the requirements of § 71.12(b) and 71.101(b) of this chapter.

[60 FR 50264, Sept. 28, 1995, as amended at 62 FR 28973, May 28, 1997; 67 FR 3586, Jan. 25, 2002; 68 FR 58818, Oct. 10, 2003]

#### § 71.103 Quality assurance organization.

(a) The licensee<sup>3</sup> shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the pro-

gram. The licensee shall clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

(b) The quality assurance functions are—

(1) Assuring that an appropriate quality assurance program is established and effectively executed; and

(2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the safety-related functions have been performed correctly.

(c) The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to—

(1) Identify quality problems;

(2) Initiate, recommend, or provide solutions; and

(3) Verify implementation of solutions.

(d) The persons and organizations performing quality assurance functions shall report to a management level that assures that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided.

(e) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom.

(f) Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.

<sup>3</sup>While the term “licensee” is used in these criteria, the requirements are applicable to whatever design, fabrication, assembly, and testing of the package is accomplished with respect to a package prior to the time a package approval is issued.